EXHIBIT 27

K102890

OCT 21 2010

SPECIAL 510(K): DEVICE MODIFICATION SUMMARY

September 29, 2010

1. SUBMITTER

KAWASUMI LABORATORIES, INC.
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U.S. AGENT:

KAWASUMI LABORATORIES AMERICA, INC
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CONTACT: Mr. Jack Pavlo

2. NAME OF DEVICE: Kawasumi Laboratories Small Vein Infusion Set with Antineedle Stick Protector and Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector
COMMON NAME: Winged Collection Set, Small Vein Set
PROPRIETARY NAME: K-Shield Small Vein Infusion Set with Antineedle Stick Protector and K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector
[Note: K-Shield is a Registered Trademark for the Kawasumi brand of needle protection devices.]
CLASSIFICATION: Class II, Codified at 21 CFR 880.5540.
PRODUCT CODE NUMBER: FPA

3. PREDICATE DEVICE: Kawasumi Laboratories Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector, and , Small Vein Infusion Set with Antineedle Stick Protector (K023917) and Becton Dickinson Vacutainer Brand Safety-Lok Blood Collection Set (K980414).

4. DESCRIPTION OF THE DEVICE: The K-Shield Small Vein Infusion Set with Antineedle Stick Protector and the K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector are sterile, single use devices commonly used to access a patient's veins for blood collection or solution infusion. Both devices are comprised of a needle and wing assembly with tubing and a female luer connector. The Multisample Luer Connector is used to transfer blood from the Winged Collection Set to a vacuum tube. Both devices incorporate an integral antineedle stick protector used to prevent accidental needlestick injuries.

5. SIGNIFICANT PERFORMANCE CHARACTERISTICS: There are no new performance characteristics of this device compared to the substantially equivalent devices marketed for sale in interstate commerce. Both devices are used to access a patient's vein for blood collection or solution infusion and provide an integral antineedle stick protector feature.

6.. INDICATIONS FOR USE: The K-Shield Small Vein Infusion Set with Antineedle Stick Protector is used to access a patient's vein for solution infusion. The device incorporates an integral, active antineedle stick protector. The K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector is used to access a patient's vein for blood sampling. The device incorporates an integral, active antineedle stick protector

7.TECHNOLOGICAL CHARACTERISTICS: The design and technological characteristics of the K-Shield Small Vein Infusion Set with Antineedle Stick Protector and the K-Shield Winged Collection Set with Multisample Luer Connector and Antineedle Stick Protectorg are substantially equivalent to the identified predicate devices. The design technological characteristics of the K-Shield devices are identical to K023917 with the exception of the modification to the antineedle stick protector design which is streamlined to remove the barrel wings and slits. This modification simplifies the needle removal process and has no significant impact on safety or effectiveness of the devices performance for their intended use.

8. SUMMARY OF NON-CLINICAL TESTING DATA: The following testing was performed to determine the safety and effective of the Small Vein Infusion Set with Antineedle Stick Protector and the Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector and assess the product's substantial equivalence to the listed predicate devices:

Test	Result
Kawasumi Internal Test: Wing Activation	PASS
Kawasumi Internal Test: Wing Deactivation	PASS
Kawasumi Internal Test: Defeat Llocking Mechanism	PASS

9. SIMULATED CLINICAL OBSERVATIONS: Kawasumi Laboratories performed a simulated use study to determine the safety and effectiveness of the Antineedle Stick Protector for use with winged needle sets. The study objectives were to identify possible antineedle stick protector design problems, and /or directions for use and labeling deficiencies, and to gain information for designing a user training program to facilitate proper use of the antineedle stick protector in the clinical setting.

Results: The simulated use study was successful. No needle sticks occurred during the trial. Comments on the Questionnaires did not indicate any problems in using the proposed Kawasumi winged needle sets with antineedle stick protectors.

10. PERFORMANCE DATA: Kawasumi Laboratories believe that the results of these tests show the device is suitable for its intended use.

11. CONCLUSIONS: The K-Shield Small Vein Infusion Set with Antineedle Stick Protector and the Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector are substantially equivalent to the identified predicate devices and perform as well as the predicate devices Small Vein Infusion Set with Antineedle Stick Protector and the Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jack Pavlo
Manager of Technical Affairs
Kawasumi Laboratories America, Incorporated
4723 Oak Fair Boulevard
Tampa, Florida 33610

OCT 2 1 2010

Re: K102890
Trade/Device Name: K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 29, 2010
Received: September 30, 2010

Dear Mr. Pavlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 1 2010

510(k) Number (if known): K102890

Device Name: K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector

Indications For Use: The K-Shield Winged Collection Set with Multisample Luer Adapter and Antineedle Stick Protector intended use is for the access of peripheral veins for blood collection. The antineedle stick protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield the needle.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/15/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102890

Indications for Use

OCT 2 1 2010

510(k) Number (if known): K102890

Device Name: K-Shield Small Vein Infusion Set with Antineedle Stick Protector

Indications For Use: The K-Shield Small Vein Infusion Set with Antineedle Stick Protector intended use is for the access of peripheral veins for solution infusion. The antineedle stick protector is an integral, active safety device intended to minimize accidental needle stick injuries when used to shield the needle.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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